



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

SEP 18 1998

6 2 6 4 '98 SEP 21 P1:51

Ms. Barbara Lynn Cantor  
Manager, Regulatory Affairs  
Bayer Corporation  
Consumer Care Division  
36 Columbia Road  
P.O. Box 1910  
Morristown, New Jersey 07962-1910

Dear Ms. Cantor:

This is in response to your letter of September 15, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Bayer Consumer Care Division is marketing the dietary supplement "One-A-Day Cold Season Dietary Supplement" labeled with claims that it "supports your body's natural defenses" and "is to support your body's natural immune system."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product by use of the term "Cold Season" suggests that it is intended to prevent, treat or mitigate disease, namely the common cold. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B) and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also indicates that you are making a claim of a relationship between calcium and osteoporosis and bone loss for the product "One-A-Day Bone Strength Dietary Supplement." This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a claim subject to section 21 U.S.C. 343(r)(1)(B) for which FDA has authorized a health claim under 21 U.S.C. 343(r)(5)(D) (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary

978-0163

LET 219

Page 2 - Ms. Barbara Lynn Cantor

supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, New Jersey District Office, Office of Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (File)  
HFS-450 (file, r/f, OSN#61209)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
GCF-1 (Nickerson, Dorsey)  
f/t:HFS-456:rjm:9/16/98:docname:61209.adv:disc32

## Consumer Care Division

Bayer Corporation  
36 Columbia Road  
P.O. Box 1910  
Morristown, NJ 07962-1910  
Phone: 973 254-5000

15 September, 1998

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204



### 30-day Post Market Notification

<b>Product Name:</b>	One-A-Day® Cold Season Dietary Supplement
<b>Name/address of distributor:</b>	Bayer Corporation, Consumer Care Division 36 Columbia Road, P. O. Box 1910 Morristown, NJ 07962-1910
<b>Name of dietary ingredient/supplement (subject of the statement):</b>	<b>Text of statement being made:</b>
One-A-Day® Cold Season Dietary Supplement	Supports your body's natural defenses* <sup>†</sup>
Zinc	to support your body's natural immune system* <sup>†</sup>
<sup>†</sup> By defending against dietary zinc insufficiency	
<b>*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.</b>	

Per the listed items in 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer Consumer Care Division has substantiation, on file, that the statement is truthful and not misleading. (This notification is comprised of an original and two (2) copies.)

Barbara Lynn Cantor  
Manager, Regulatory Affairs

cc: C. Hammes, D. Christensen, R. Cuprys, T. Glass, J. Kindel, file

h:\...\30dnote3.doc

61209

## Consumer Care Division

Bayer Corporation  
36 Columbia Road  
P.O. Box 1910  
Morristown, NJ 07962-1910  
Phone: 973 254-5000

15 September, 1998

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204



### 30-day Post Market Notification

<b>Product Name:</b>	One-A-Day® Bone Strength Dietary Supplement
<b>Name/address of distributor:</b>	Bayer Corporation, Consumer Care Division 36 Columbia Road, P. O. Box 1910 Morristown, NJ 07962-1910
<b>Name of dietary ingredient/supplement (subject of the statement):</b>	<b>Text of statement being made:</b>
One-A-Day® Bone Strength Dietary Supplement	Helps prevent bone loss*
Vitamin D	to help calcium absorption
Calcium	to reduce the risk of osteoporosis <sup>†</sup>
Soy Extracts	diets that include soy may help promote bone health*
<sup>†</sup> Osteoporosis is a reduction in the amount of bone mass, related to bone fractures later in life. This disease affects middle-aged and older individuals. Those at increased risk of developing osteoporosis include: white and Asian women during their teen, young adult, menopausal and post-menopausal years; as well as those individuals with a family history of the disease; and the elderly. A lifetime of regular exercise and a healthy diet with adequate calcium intake will help build and maintain good bone health and may reduce the risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above 2,000 mg are not likely to provide any additional benefit.	
<b>*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.</b>	

Per the listed items in 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer Consumer Care Division has substantiation, on file, that the statement is truthful and not misleading. (This notification is comprised of an original and two (2) copies.)

  
\_\_\_\_\_  
Barbara Lynn Cantor  
Manager, Regulatory Affairs

cc: C. Hammes, D. Christensen, R. Cuprys, T. Glass, J. Kindel, file

h:\...\30dnote7.doc

61209